

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

In re AbbVie Inc., et al.

)
) Case No. 14-cv-1748
) Honorable Matthew F. Kennelly
)

This Document Relates to All Cases

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS**

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INTRODUCTION

Defendants' testosterone replacement therapies—TRTs, for short—are FDA-approved prescription medications that are used to raise testosterone levels in men whose bodies produce little or none. These medicines offer relief from the effects of documented low testosterone, which include fatigue, loss of muscle, and fragile bones. Decades of scientific literature also shows that increasing testosterone levels in men with low testosterone may help *avoid* cardiovascular problems such as heart attack and stroke. Plaintiffs here assert, in all but identical complaints, the exact opposite. They say TRTs *caused* a variety of their cardiovascular problems, without ever mentioning the decades of scientific literature contradicting that claim.

Causation. This motion seeks dismissal of all of the complaints, because they uniformly fail to make factual allegations that TRTs actually caused their problems. When a plaintiff's injury has a variety of potential causes, as is plainly the case here, a complaint must be dismissed if it fails to allege facts plausibly pinpointing the specific asserted cause. *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007); *Dura Pharms. v. Broudo*, 544 U.S. 336, 347 (2005).

Cardiovascular problems can be caused by a variety of factors having nothing to do with TRTs. There are many well-known risk factors, such as cholesterol levels, blood pressure, blood sugar levels, tobacco or alcohol use, diet, physical inactivity, obesity, genetic factors, and family history. No Plaintiff addresses any of these risk factors. The complaints never even mention them.

Instead, notwithstanding decades of research showing the opposite, the complaints focus on three recent studies that purport to explore a possible association between TRTs and an increased risk of cardiovascular problems. These studies cannot provide plausible causation, for two reasons.

First, none of the studies find any increased risk for the class of patients that includes Plaintiffs. On the contrary, one of the studies—in the *PLoS One* journal in 2014—explicitly found ***no*** increased risk of heart attack for healthy patients under age 65: “In men under age 65 years, excess risk was confined to those with a prior history of heart disease.” Here, all but one

of the 39 Plaintiffs are under age 65, and none allege any history of heart disease. So this study cannot support their causation allegation.

Plaintiffs also rely on a study published in the *New England Journal of Medicine* in 2010, which likewise offers them no help. It was a study of testosterone's effect on strength and physical function in frail elderly men who could not walk two blocks or climb ten steps. The men were all 65 or over, with an average age of 74, and they had high levels of heart disease, high blood pressure, diabetes, and obesity—all serious risk factors for cardiovascular problems. Again, all but one of the Plaintiffs are under 65, and none allege having any of those risk factors or mobility problems.

The third study, in the *Journal of the American Medical Association* in 2013, is equally irrelevant. That study looked back at medical records from Veterans Affairs facilities for veterans with serious health problems: 20 percent had a prior heart attack, half were diabetic, and over 80 percent had coronary heart disease. Again, no Plaintiff alleges having those conditions.

Second, the three studies suffered from admitted limitations and deficiencies that do not support associating TRTs with cardiovascular problems for *any* patients, much less for patients like Plaintiffs. For instance, despite asserting a possible connection between TRTs and cardiovascular problems, the *NEJM* study's authors concede that their asserted connection "may have been due to chance alone." The study was stopped after the testosterone group experienced a higher rate of cardiovascular issues than the placebo group, but those issues included things such as fainting that no Plaintiff has alleged. And the study's authors confessed its shortcomings: no structured evaluation of cardiovascular problems was performed, the sample size was small, and the participants were not representative of the healthy 65-and-under population. It was not even a study of cardiovascular problems. The authors expressly acknowledged that the study did **not** provide scientific evidence regarding the safety of TRTs: "[t]he small size of the trial and the unique population prevent broader inferences from being made about the safety of testosterone therapy."

The *JAMA* study was a retrospective examination of medical records, not a controlled clinical trial, so testosterone was *not* given randomly to the patients, and no placebo control group was used. The study suffered from blatant errors, such as including 100 women in the group of patients that was supposed to include only men. And only 13 out of 8,700 patients in the study used testosterone gel, which is the form of TRT used by *every* Plaintiff that is the subject of this motion to dismiss. The study did not report whether even a single gel user suffered any problem. And, in the end, the actual rate of cardiovascular problems in the testosterone group was *less than half* that of the non-testosterone group. The senior investigator, Dr. Michael Ho, was interviewed in the medical trade press and specifically *disclaimed* proof of causation: “We found an association; *it’s not causal*, given the observational nature of the study.” One expert scientific body, the Androgen Study Group, recently concluded that the *JAMA* study and the *PLoS One* study were “without scientific merit.” The chairman of the Androgen Study Group found the studies to be “so flawed” that they “represent[ed] non-science, or its close cousin, nonsense.” Again, these studies provide no plausible basis for blaming TRTs for the Plaintiffs’ alleged problems.

In sum, these three flawed studies, none of which addressed patients similar to Plaintiffs, provide no plausible basis for Plaintiffs’ allegation that TRTs rather than a host of other common risk factors caused their cardiovascular problems.

Failure To Warn. Even putting aside the issue of causation, the complaints should be dismissed for other reasons. Many of the causes of action rely on the theory that Defendants failed to warn Plaintiffs about an increased risk of cardiovascular problems. But under the learned intermediary doctrine, the only required warning is a warning to doctors, and the complaints contain no allegations on this subject: no allegations about what information each Plaintiff’s doctor received, reviewed, and disclosed to him; about what warning should have been provided; and, most importantly, about why such a warning would have prevented each individual doctor from prescribing TRTs to each individual Plaintiff. Courts around the country recognize that the lack of these allegations dooms claims that are based on an alleged failure to

warn. The failure-to-warn claims also suffer from other defects. For example, some Plaintiffs allege blood clots or injuries resulting from blood clots, but the full Prescribing Information already warns about the potential risk of blood clots and the specific steps that should be taken to mitigate that risk.

Fraud-Based Claims. Every complaint includes multiple causes of action sounding in fraud, but no complaint articulates with the particularity that Rule 9(b) requires the facts about what was said, who said it, when it was said, why it was false, and how each Plaintiff relied on it and was injured by it. Instead, the complaints rely on generic boilerplate allegations about deceiving the Plaintiffs and hiding “true facts.” All causes of action sounding in fraud should be dismissed.

State Law Issues. Finally, many of the causes of action fail under the state laws that govern them—each Plaintiff’s own home state’s laws. The defects here are too many to summarize in an introduction, but a few examples will suffice. One Plaintiff is from Michigan, which does not allow any claims to be asserted about FDA-approved drugs such as TRTs. Another two Plaintiffs are from Kansas, which allows product liability plaintiffs to allege only one cause of action, for strict liability; all other causes of action must be dismissed. Another Plaintiff is from Massachusetts, which as a matter of law does not recognize the claim for strict liability that he asserts. Every Plaintiff brings a claim for breach of express warranty, yet no Plaintiff alleges the content of that warranty or how he relied on it. And so on. It is clear that the causes of action in the complaints are boilerplate, asserted without any regard to the laws that govern them.

For all of these reasons and those stated below, Defendants respectfully urge the Court to dismiss the complaints.

BACKGROUND

A. Hypogonadism and TRTs

Hypogonadism is a medical condition, which in men is characterized by having low or no testosterone. Symptoms can include loss of muscle, fragile bones, and fatigue.¹

A large body of literature from the last 20 years, ignored by the complaints, links low testosterone levels to cardiovascular problems such as heart attack and stroke. The literature also shows that increasing testosterone in men with low testosterone levels is associated with a lower risk of cardiovascular problems. One recent article reviewed over 100 studies and found that low levels of testosterone are associated with higher rates of mortality, including from cardiovascular problems.² Another recent study found that men with hypogonadism who used TRTs experienced a 10.3 percent mortality rate, while the mortality rate for men who did not use TRTs was 20.7 percent.³ And another recent study similarly found that among men with low testosterone levels, men who were treated with testosterone had lower mortality (8.4 percent) than untreated men (19.2 percent).⁴

For the past 20-plus years, FDA-approved TRTs for men with hypogonadism have been on the market. Each Defendant filing this motion provides FDA-approved TRTs. Those therapies, which require a prescription, can be found in various forms, including gels, injectable

¹ THE MAYO CLINIC, *Male hypogonadism* (Apr. 1, 2014), <http://www.mayoclinic.org/diseases-conditions/male-hypogonadism/basics/symptoms/con-20014235>. The court may take judicial notice of the undisputed medical facts mentioned in this brief. *McDonnell v. First Unum Life Ins.*, 2013 WL 3975941, at *16 n.33 (S.D.N.Y.) (“the Court takes judicial notice of this background information on Lyme Disease, its diagnosis, and its treatment”); *Harris v. Lappin*, 2009 WL 789756, at *12 (C.D. Cal.) (judicial notice of disease information); *Banks v. County of Allegheny*, 568 F. Supp. 2d 579, 596-97 (W.D. Pa. 2008) (judicial notice of facts about drugs).

² Peyman Mesbah Oskui et al., *Testosterone and the Cardiovascular System: A Comprehensive Review of the Clinical Literature*, 2 J. AM. HEART ASS’N 18 (2013).

³ Molly M. Shores et al., *Testosterone Treatment and Mortality in Men with Low Testosterone Levels*, 97 J. CLIN. ENDOCRINOL. METAB. 2050, 2050 (2012).

⁴ Vakkat Muraleedharan et al., *Testosterone deficiency is associated with increased risk of mortality and testosterone replacement improves survival in men with type 2 diabetes*, 169 EUR. J. ENDOCRINOL. 725, 725 (2013).

medications, patches, and tablets. All of the therapies at issue here are in gel form: AndroGel from AbbVie,⁵ Axiron from Eli Lilly, Testim from Auxilium Pharmaceuticals, and Fortesta from Endo Pharmaceuticals.

B. Lawsuits alleging personal injury

These lawsuits all allege personal injuries from using TRTs. This motion addresses 39 of the cases consolidated in this Court, as specified in Pretrial Order No. 2, paragraph 4. This motion accepts as true all of the well-pleaded factual allegations of the complaints.

The complaints have very similar allegations and are essentially identical in substance, so this motion uses one of them, the *Marino* complaint (1:14-cv-777), as an example. *Marino* alleges that hypogonadism is a “specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.” *Id.* ¶ 19. AbbVie is alleged to have used a successful marketing campaign to increase men’s awareness about low testosterone. *Id.* ¶¶ 3, 22-33, 48-50. As a treatment, AbbVie sells two versions of AndroGel: a 1% concentration that FDA approved in 2000 and a 1.62% concentration that FDA approved in 2011. *Id.* ¶ 38.

Every Plaintiff claims to have used AndroGel. A few Plaintiffs allege they also used a second TRT: Cataudella claims to have used Fortesta, Parker claims to have used Testim, and Lau claims to have used Axiron.

The *Marino* complaint, like every other complaint, says practically nothing about Plaintiff’s own use of TRTs. Marino was 50 when he was prescribed AndroGel for “symptoms he attributed to low testosterone.” *Id.* ¶ 55. Although he had “no history” of cardiac problems, he later suffered a “transient ischemic attack”—a mini-stroke. *Id.* ¶¶ 57-58.

That is everything the *Marino* complaint alleges on the subject. It does not allege anything about the concentration of the AndroGel he used (that is, which specific drug he used), how often and for how long he used it, who prescribed it for him, what information the

⁵ AbbVie was established at the beginning of 2013 as an independent, publicly traded company from the pharmaceutical business of co-defendant Abbott Laboratories, which no longer sells AndroGel in the United States.

prescribing doctor reviewed or conveyed to him, when he had the mini-stroke, what other risk factors he had for mini-strokes, and so on.

To summarize the allegations of all 39 Plaintiffs, the chart found at Appendix A provides each Plaintiff's last name, injury, age, TRT used, and state of residence.

Injury. Some Plaintiffs, like Marino, allege a mini-stroke. Other Plaintiffs allege stroke, myocardial infarction (heart attack), blood clot (including deep vein thrombosis and pulmonary embolism)⁶, or a related medical problem. All but eight Plaintiffs allege they had “no history” of those conditions. Four—Covey, DeForest, Dula, and Parker—allege nothing about their histories. The last Plaintiff, Darby, does not allege anything about his history but alleges he was “very healthy” and in “excellent physical condition.”

States of residence. The 39 Plaintiffs live across the country, in 23 different states.

Age. Only one Plaintiff, Cataudella, reported an age of 65 or older when he was prescribed TRT and suffered his alleged injury. The remaining Plaintiffs' ages range from 39 to 63. Two Plaintiffs—LaRoche and Parker—did not allege information about their ages.

C. Causation

As their sole basis for alleging that TRTs caused Plaintiffs' alleged medical problems, the complaints rely on three studies. This section addresses those studies.⁷

1. The *NEJM* study (2010)

The first study, attached as Exhibit 1, appeared in the July 2010 issue of the *New England Journal of Medicine*. The complaints state, without further detail, that this study was

⁶ Deep vein thrombosis refers to a blood clot in a large vein, usually in the leg or pelvis. Pulmonary embolism refers to a blood clot that travels through the bloodstream into the lungs. CENTERS FOR DISEASE CONTROL, *What is DVT?*, http://www.cdc.gov/ncbddd/dvt/documents/dvt-factsheet_final1210.pdf.

⁷ Although the studies were not physically attached to the complaints as exhibits, the complaints explicitly rely on the studies, so the studies may be considered in this motion. *Wright v. Assoc. Ins.*, 29 F. 3d 1244, 1248 (7th Cir. 1994) (when ruling on a motion to dismiss, district court may consider documents that are “referred to in the plaintiff's complaint and are central to his claim”).

“discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.” Marino Compl. ¶ 35.

The *NEJM* study was *not* a study of the risk of cardiovascular problems from TRTs. Instead, it looked at “the effects of testosterone administration on lower-extremity strength and physical function in older men with limitations in mobility” and low testosterone. Ex. 1 at 110. The study participants were all frail men ages 65 and over, with an average age of 74, who could not walk two blocks or climb ten steps. *Id.* at 110-111. In these men there was a high prevalence of pre-existing heart disease, high blood pressure, diabetes, and obesity, all conditions that are serious risk factors for cardiovascular problems. *Id.* at 109.

The study was discontinued when participants in the testosterone group suffered a greater number of “cardiovascular events” than participants in the placebo group. *Id.* at 110. These “cardiovascular events” were mostly issues, such as fainting, that have not been alleged by Plaintiffs. *Id.* Table 3.

The study’s authors cautioned that the “generalizability of our data about the safety of testosterone therapy is limited by several factors.” *Id.* at 116. First, cardiovascular events were not the subject of the study. “[T]herefore, a structured evaluation of cardiovascular events was not performed, a factor that may have influenced the ascertainment of events.” *Id.*

Second, the sample size “was small, and the number of adverse events was small,” *id.* at 117, which contradicts Plaintiffs’ allegation that an “exceedingly high number of men in the testosterone group suffered adverse events.” Marino Compl. ¶ 35. “The results of individual small trials may not be confirmed in large trials, and trials that have been stopped early tend to overestimate treatment differences.” Ex. 1 at 117.

Third, the participants were drawn from a non-representative population. “[T]he clinical characteristics of our study population differ from those of *most other populations* in which testosterone therapy has been administered in a clinical setting or as part of a clinical trial. Men who were younger than 65 years of age and men with severe hypogonadism were excluded from the trial. Participants had substantial limitations in mobility and a high prevalence of chronic

conditions, including preexisting heart disease, obesity, diabetes, and hypertension. Frail elderly men with limitations in mobility are more likely to have clinical and subclinical cardiovascular disease than are those who do not have limitations in mobility.” *Id.* (emphasis added).

In sum, the study’s authors admitted that “[t]he small size of the trial and the unique population prevent broader inferences from being made about the safety of testosterone therapy” and that the higher numbers of cardiovascular events in the testosterone group “may have been due to chance alone.” *Id.* at 118. They urged “[c]aution ... in extrapolating these findings ... to other populations, particularly young men who have hypogonadism without cardiovascular disease or limitations in mobility.” *Id.* at 117-118. And the senior investigator, Dr. Michael Ho, specifically disclaimed proof of causation: “We found an association; it’s not causal, given the observational nature of the study.”⁸ In other words, caution in extrapolating any findings to the Plaintiffs in these cases, particularly given that the cardiovascular events noted in the *NEJM* study were not limited to heart attacks but also included instances of fainting (syncope), elevated blood pressure, and rapid heart rate, among other things. *Id.* at Table 3.

2. The JAMA study (2013)

The second study, attached as Exhibit 2, appeared in November 2013 in the *Journal of the American Medical Association (JAMA)*.⁹ The complaints state, without detail, that it found TRTs raise “the risk of death, heart attack and stroke by about 30%.” Marino Compl. ¶ 36.

The *JAMA* study was a retrospective study, looking back at medical records from Veterans Affairs facilities of “male veterans who underwent coronary angiography^[10] between

⁸ Michael O’Riordan, *Testosterone Therapy Linked With Adverse CVD Events*, HEARTWIRE (Nov. 5, 2013), <http://www.medscape.com/viewarticle/813833>.

⁹ As explained below, the deeply flawed *JAMA* study has been corrected several times. The version attached as Exhibit 2 is the corrected version, up to date as of the date of this motion.

¹⁰ Coronary angiography is a test that uses special x-rays to see blockages in the coronary arteries (the blood vessels that supply oxygen to the heart) from the buildup of plaque, which is known as coronary heart disease. NAT’L INSTITUTES OF HEALTH, *What Is Coronary Angiography?* (Mar. 2, 2012), <http://www.nhlbi.nih.gov/health/health-topics/topics/ca/>.

2005 and 2011 and who had a testosterone level checked” that was found to be low. Ex. 2 at 1830. There were just over 8,700 such veterans with low testosterone. *Id.* at 1831.

The study reports that these veterans had “a high burden of comorbidities”—in other words, many of them already had serious diseases that often lead to heart attacks, strokes, and similar problems. *Id.* Twenty percent had a prior myocardial infarction (a heart attack), half were diabetic, and over 80 percent had coronary heart disease. *Id.*

Unlike in a clinical trial, testosterone therapy and placebos were **not** given randomly: “patients were not randomized to receive testosterone therapy.” *Id.* at 1831. A total of 1,223 patients were prescribed testosterone therapy; the other 7,486 patients were not. *Id.* at 1833.

The study “assumed” that once a patient received a prescription, he “continued treatment until an outcome event [such as heart attack] occurred or the end of follow-up” in January 2012. *Id.* at 1830. Yet 215 of the patients only filled one prescription. *Id.* at 1833. And only 60 percent of patients had their testosterone values checked after starting treatment, *id.*, which is the only way to know what effect the medication is having on testosterone levels in the body.

Nor were the various *forms* of TRTs given randomly to these veterans. Only 13 patients were prescribed testosterone gel. *Id.* at 1832. Veterans Affairs facilities do **not** use AndroGel.¹¹ The study also did not report how many of the 13 testosterone gel patients filled more than one prescription, or whether **any** of the testosterone gel patients experienced **any** medical problem.

The study compared the cumulative percentages of death, heart attacks, and strokes between the TRT group and the non-TRT group. *Id.* at 1832. The study did not include any other medical problems, such as blood clots, or, more specifically, deep vein thrombosis or pulmonary embolism, which are alleged in some of the complaints.

The actual rate of adverse events in the group using TRTs was **less than half** that of the non-TRT group, a result consistent with prior studies. In the TRT group, there were 123 adverse

¹¹ The Veterans Affairs National Formulary can be found at <http://www.visn20.med.va.gov/wwwrx/NonFormularyByClassForWeb.pdf>. On page 113 of 180, it states, for AndroGel: “Non-Formulary: no criteria for use.”

events in the 1,223 patients, for a rate of 10.1 percent. *Id.* In the non-TRT group, there were 1,587 adverse events in the 7,486 patients, for a rate of 21.2 percent. *Id.* But the study’s authors inexplicably used complex statistical adjustments to “interpret” those numbers as showing that the TRT group faced an **increased** risk over the non-TRT group.

After applying those complex statistical adjustments, the study “estimated” the following percentages of the specified medical problems as of one year, two years, and three years:

	No Testosterone	Testosterone	Absolute Risk Difference	Risk Difference at 95 Percent Confidence Interval
One year	10.1%	11.3%	1.3%	-7.1 to 9.7%
Two years	15.4%	18.5%	3.1%	-4.9 to 11.0%
Three years	19.9%	25.7%	5.8%	-1.4 to 13.1%

Id. A 95 percent confidence interval for an estimate indicates that if the figure were re-estimated repeatedly, it would fall within the given range 95 percent of the time.¹² Given that the 95 percent confidence interval extends into negative values in each time period (shown in **bold** on the chart), the TRT group would sometimes be estimated, even after the complex statistical adjustments, to have **lower** risk than the non-TRT group.

The study’s authors admitted that it was “the first observational study ... to suggest that testosterone therapy is associated with adverse cardiovascular outcomes.” *Id.* at 1834. A prior retrospective study of Veterans Affairs medical records, from just one year earlier, “noted a **39% reduction** in mortality risk among patients treated with testosterone therapy.” *Id.* (emphasis added). Notably, compared to the patients in the *JAMA* study, the patients in that earlier study had fewer prior cardiovascular problems. *Id.* This is an important point, because **no** Plaintiff reports having prior cardiovascular problems—indeed, almost all of them affirmatively allege that they had “no history” of such problems.

¹² U.S. CENSUS BUREAU, *A Basic Explanation of Confidence Intervals* (Apr. 29, 2013), <http://www.census.gov/did/www/saife/methods/statecounty/ci.html>.

The *JAMA* study's authors admitted several weaknesses in the study. These included the fact that it was only an observational study; the medical records may have underestimated the patients' testosterone levels; and the patients who participated were drawn from a very specific group (angiography patients in VA facilities), which "limits generalizability" to other groups. *Id.* at 1834-35.

The *JAMA* study has been widely criticized in the medical community, and there is now a petition, signed by dozens of medical societies, to have it retracted.¹³ The admitted errors in the study—one of which was including **100 women** in a study about male TRT¹⁴—have already resulted in two public corrections. Moreover, not only were the men in the study already in poor health (all had undergone cardiac catheterization, and 55 percent had obstructive coronary artery disease),¹⁵ many of them continued to have low testosterone even after using TRTs, *id.* at 1833, raising the possibility that they were at risk for cardiovascular events by virtue of their medical histories and low testosterone, rather than because of medical treatments.

3. The *PLoS One* study (2014)

The third study, attached as Exhibit 3, appeared in January 2014 in the *PLoS One* journal. The complaints state, without further detail, that the *PLoS One* study found that TRTs "doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease." Marino Compl. ¶ 37. The complaints fail to mention that

¹³ Early news of the petition is available at <http://www.prnewswire.com/news-releases/twenty-five-medical-societies-join-androgen-study-group-to-petition-jama-to-retract-misleading-testosterone-study-254707661.html>. A current list of signatories, including a very large number of medical doctors and Ph.Ds, can be found at <http://www.androgenstudygroup.org/pdf/list-cosigners-androgen-study-group-initiative.pdf>.

¹⁴ See the correction at <http://jama.jamanetwork.com/article.aspx?articleid=1835478>. The warning labels for testosterone gels warn women against even "secondary exposure"—that is, touching a man's skin where the gel was applied.

¹⁵ Josh Trutt, *Does Testosterone Cause Heart Attacks? A Response to JAMA*, TRUTTMD.COM (Nov. 6, 2013), <http://truttmd.com/testosterone-cause-heart-attacks-response-jama/>.

the *PLoS One* study found **no** increased risk of heart attack for healthy men under age 65, which is **every single Plaintiff** who alleges a heart attack.

The *PLoS One* study examined a database of health care records for a group of men who were prescribed TRTs. Ex. 3 at 2. It compared those records to records for men who were prescribed erectile dysfunction drugs. *Id.* The study thus lacked a proper control group consisting of similarly situated men who were not prescribed TRTs. In addition, the available data were quite limited: “[n]o data were available on indications for [TRT] prescription, race, laboratory findings, occupational, environmental, or lifestyle factors.” *Id.* The study’s authors, in other words, had **no** information about obesity, smoking, and the many other risk factors for the heart attacks they were studying. The study relied on International Statistical Classifications of Diseases codes (ICD-9 codes) for myocardial infarction (heart attack), and included patients coded at outpatient clinics, so it is unknown if any of these people actually experienced a heart attack. *Id.* The study authors also did not know any details about the patients’ heart attacks, including when they occurred in relation to the patients’ use of TRTs. *Id.*

The study looked only at the risk of non-fatal heart attacks, *id.* at 1, not death or stroke or any other medical problem alleged in the complaints. It claimed to find an increase in risk of non-fatal heart attack in TRT patients older than 65, as well as in TRT patients younger than 65 who also had a history of heart disease. *Id.* at 4. But the study detected **no** increased risk for men under 65 without prior heart disease. *Id.* According to the allegations of the complaints, **every** Plaintiff who alleges a heart attack was under 65, and none had prior heart disease.

The authors acknowledged that “there is some evidence that low *endogenous* testosterone levels may also be positively associated with cardiovascular events.” *Id.* at 6. That is, studies have associated **low** testosterone, resulting from a condition in the body, with a **greater** number of cardiovascular problems such as heart attack. *Id.* The authors admitted that they were “unable to examine whether this excess [risk of heart attack that they claimed to find in the study] was related to indications such as the level of serum [that is, blood-based] testosterone or hypogonadism.” *Id.* Finally, the authors also acknowledged that the study has “limitations related

to the use of a health-care database that did not include [certain] information” and was not based on “a structured evaluation as might occur in a randomized trial.” *Id.*

D. Causes of action

The complaints allege that TRTs caused Plaintiffs’ medical problems and Defendants knew (or should have known) and should have warned about those risks. Marino Compl. ¶¶ 2, 17, 53. Based on that theory, most of the complaints allege the same six causes of action: (1) strict liability—failure to warn, (2) negligence, (3) breach of implied warranty, (4) breach of express warranty, (5) fraud, and (6) negligent misrepresentation. *Id.* ¶¶ 59-88.¹⁶ Fourteen complaints add a spouse’s claim for loss of consortium. Two complaints (*LaRoche* and *Lueck*) add a wrongful death or survival action claim because the Plaintiff is deceased. Just one complaint (*Darby*) adds other causes of action: defective design, manufacturing defect, failure to test, and intentional and negligent infliction of emotional distress.

Given that every complaint asserts a failure to warn, it is proper on a motion to dismiss to consider the actual warnings given.¹⁷ This section explains the relevant warnings, from the prescribing information for AndroGel 1% that is provided to doctors, because every Plaintiff used AndroGel, and because the warnings do not differ materially, for the points made in this motion, from the warnings for the other TRTs. The prescribing information for AndroGel 1% is attached as Exhibit 4.¹⁸ It contains two provisions of note for this motion.

¹⁶ In a few cases, one or more of the standard six causes of action is divided into parts. An example is the division of fraud into separate causes of action for fraudulent misrepresentation, fraudulent concealment, and fraud and deceit. This issue affects some causes of action in the *Covey*, *Darby*, and *DeForest* complaints. It has no effect on the arguments made in this motion.

¹⁷ See, e.g., *Mills v. Bristol-Myers Squibb*, 2011 WL 3566131, at *3 (D. Ariz.) (judicial notice of a drug label); *Adamson v. Ortho-McNeil Pharm.*, 463 F. Supp. 2d 496, 500–01 (D.N.J. 2006) (same); *Salvio v. Amgen*, 810 F. Supp. 2d 745, 750-51 (W.D. Pa. 2011) (same); *Gen. Elec. Capital Corp. v. Lease Resolution*, 128 F.3d 1074, 1080–81 (7th Cir. 1997) (judicial notice of “undisputed fact in the public record”). AndroGel prescribing information, for example, is available publicly on AbbVie’s website. See http://www.rxabbvie.com/pdf/androgel_PI.pdf (AndroGel 1%); http://www.rxabbvie.com/pdf/androgel1_62_PI.pdf (AndroGel 1.62%).

¹⁸ The prescribing information for the other TRTs and AndroGel 1.62% are attached as Exhibit 5.

Blood clots. First, physicians are notified that “[i]ncreases in hematocrit,^[19] reflective of increases in red blood cell mass, may require lowering or discontinuation of testosterone” because “[a]n increase in red blood cell mass may increase the risk of *thromboembolic events*.” *Id.* (emphasis added). Thromboembolic events are blood clots, and include deep vein thrombosis and pulmonary embolism.²⁰ Physicians are therefore advised to test hematocrit before prescribing AndroGel, at three to six months, and annually thereafter. *Id.* “If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable concentration.” *Id.*

Patients ages 65 and over. Second, the prescribing information states that AndroGel 1%’s efficacy in patients aged 65 and over has not been studied in “sufficient numbers.” *Id.* § 8.5. It also warns that “there is insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease...” *Id.*

STANDARD OF REVIEW

To avoid dismissal under Rule 8, a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007). This means the complaint’s “factual content” must allow “the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). It is not enough to plead facts showing that a claim is “conceivable.” *Twombly*, 550 U.S. at 570. In other words, a complaint must do more than present “a sheer possibility that a defendant has acted unlawfully.” *Iqbal*, 556 U.S. at 678. Facts that are “‘merely consistent with’ a defendant’s liability” are insufficient because they “‘stop[] short of the line between possibility and plausibility of entitlement to relief.’” *Id.*, quoting *Twombly*, 550 U.S. at 557. If “well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the

¹⁹ Hematocrit refers to the percentage of blood volume that is made up of red blood cells. NAT’L INSTITUTES OF HEALTH, *Hematocrit*, (May 16, 2014), <http://www.nlm.nih.gov/medlineplus/ency/article/003646.htm>.

²⁰ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Preventing Venous Thromboembolism*, (Jan. 15, 2013), <http://www.cdc.gov/cdcgrandrounds/archives/2013/january2013.htm>.

complaint has alleged—but it has not shown—that the pleader is entitled to relief,” and the complaint must be dismissed. *Id.* at 679.

When considering whether a complaint states a plausible claim, one must put aside “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements....” *Id.* Conclusions “are not entitled to the assumption of truth,” and Rule 8 “does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” *Id.* at 678-79. Only “well-pleaded factual allegations” may “plausibly give rise to an entitlement to relief.” *Id.* at 679.

ARGUMENT

Sections I and II of this memorandum identify global defects in all of the 39 complaints, which fail to satisfy Rules 8(a) and 9(b). Section III identifies defects under the laws that govern each Plaintiff’s claims—the laws of his home state.

I. Plaintiffs fail to state a plausible claim.

A. Causation

The complaints allege that (a) Plaintiffs used TRTs and (b) at some later point suffered a heart attack, stroke, blood clot, or similar medical problem. Those bare allegations fail to state a plausible claim, so every complaint should be dismissed.

1. A complaint that fails to plead plausible causation must be dismissed.

A complaint must be dismissed if it lacks factual allegations plausibly showing that the defendant’s unlawful conduct, rather than some other cause, is responsible for the plaintiff’s injury. *Twombly* itself illustrates this principle.

In *Twombly*, the plaintiff alleged that telecommunications companies engaged in anticompetitive “parallel conduct” to inflate telephone and internet charges. *Twombly*, 550 U.S. at 550. The “crucial question” was whether this parallel conduct was the result of an independent decision at each company, which would be unobjectionable, or the result of a conspiracy among the companies, which would be illegal. *Id.* at 553. Given those two possible alternative causes, the Supreme Court refused to assume that illegal conduct was the cause: “parallel conduct does

not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality.” *Id.* at 557. The parallel conduct “could just as well be independent action.” *Id.* The Supreme Court ordered the complaint dismissed for the plaintiff’s failure to make non-conclusory, factual allegations sufficient to show that the inflated charges were actually caused by illegal conduct.

By requiring factual allegations to show which of several alternative causes was responsible for the plaintiff’s injury, the Supreme Court in *Twombly* was following and reinforcing its conclusion to that effect two years earlier in *Dura Pharmaceuticals v. Broudo*, 544 U.S. 336 (2005). There, the plaintiff alleged that he bought Dura’s stock at a price that was inflated because of false statements the company made about its products. *Id.* at 338-39. The Supreme Court recognized that when the stock’s price later fell, there were many potential causes other than an earlier misrepresentation: “that lower price may reflect, not the earlier misrepresentation, but changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price.” *Id.* at 343. Given those other potential causes, which the complaint did not address, the Supreme Court held that the complaint must be dismissed for failing the “simple test” of “pleading ... proximate causation.” *Id.* at 346.

These principles apply equally to claims that a product caused a medical problem or disease. In a case decided in April, for example, the plaintiff alleged that she developed type 2 diabetes by eating foods containing high fructose corn syrup (“HFCS”). *S.F. v. Archer-Daniels-Midland*, 2014 WL 1600414, at *1 (W.D.N.Y.). The court, heeding the Supreme Court’s admonition that “[d]etermining whether a complaint states a plausible claim for relief will ... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense,” recognized the obvious point that type 2 diabetes is “a multifactorial disease. It can be caused by, for example, a lack of exercise, genetics, or poor diet—or some combination of several factors.” *S.F.*, 2014 WL 1600414, at *3, 4 (quoting *Iqbal*, 556 U.S. at 679). Even accepting the allegations of the complaint as true, the court held “there is little in it to suggest

that Plaintiff could prove that her consumption of some foods containing HFCS over the course of her life was a substantial factor in causing Type 2 diabetes.” *Id.* It was not enough for the plaintiff to have “idly list[ed] various common foods she has eaten.” *Id.* She was required to, but did not, allege specific “facts that might lead this Court to believe that she could ultimately show that it was her consumption of ... specifically the [HFCS] within these foods ... that led to her disease.” *Id.* The court dismissed the lawsuit with prejudice. *Id.* at *9.

Last year, another court dismissed a complaint alleging that a drug caused injury because the complaint only alleged that the plaintiff took the drug and later suffered an injury, without any specific facts to support causation. *Kwasniewski v. Sanofi-Aventis U.S.*, 2013 WL 2558283, at *2 (D. Nev.). “Under the facts as presently pled in the Complaint, [plaintiff]’s death may have been caused by any number of events or factors independent of his ingestion of Ambien. Consequently, Plaintiffs’ allegation that Ambien was the direct and proximate cause of Mr. Kwasniewski’s death is conclusory and not entitled to the presumption of truth.” *Id.*

Courts across the country have reached the same conclusion. If an alleged injury has different possible causes, courts require the complaints to allege sufficient facts to show that the defendant’s conduct plausibly caused the injury.²¹

2. The complaints do not plead facts to allege plausible causation.

The theory of causation in these cases follows the well-known form of *post hoc, ergo propter hoc*: Plaintiffs used TRTs before experiencing problems, so the TRTs must have caused those problems. But *post hoc* is a logical fallacy, not the basis for a plausibly pleaded lawsuit. Under Rule 8 and *Twombly*, one may not assume, as the complaints do, that if a Plaintiff used a TRT prior to suffering a medical problem, then the medication must have caused that problem.

²¹ See, e.g., *White v. Volkswagen Grp.*, 2013 WL 685298, at *6 (W.D. Ark.) (dismissing product liability claim because the complaint failed to address a “number of plausible causes” for the injury); *Thunander v. Uponor*, 887 F. Supp. 2d 850, 870 (D. Minn. 2012) (dismissing product liability claim for failure to allege “sufficient facts” to show that the product contained “a toxin capable of causing injury to humans, let alone that Plaintiffs themselves have experienced any symptoms attributable to the alleged toxin”); *McCarthy v. Olin*, 119 F.3d 148, 152 (2d Cir. 1997) (affirming dismissal of a products liability complaint for failure to establish proximate cause).

Product liability lawsuits such as these require two types of causation: general causation (whether the product is capable of causing the type of injury) and specific causation (whether the product actually caused the plaintiff's own injury). *Amorgianos v. Nat'l R.R. Passenger*, 303 F.3d 256, 268 (2d Cir. 2002); *Ruggiero v. Warner-Lambert*, 424 F.3d 249, 250 n.1 (2d Cir. 2005); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006). The complaints do not plausibly plead either one.

a. General causation

Against the backdrop of two decades of research showing that (a) **low** testosterone is associated with an increased risk of cardiovascular problems such as heart attacks, strokes, and blood clots, and (b) increasing testosterone in men with hypogonadism leads to a **lower** rate of cardiovascular problems, the complaints do not plausibly allege that TRTs cause those problems. In fact they say almost nothing at all on that subject. Each complaint devotes just three paragraphs to it, one for each of the three studies described above. Those studies simply do not show that the use of TRTs increases the risk of cardiovascular problems.

The first, from *NEJM*, was not even a study about cardiovascular problems. It was a study of whether testosterone therapy improved severely limited mobility in men aged 65 and over who were often already beset by other serious medical problems. The adverse events experienced by the men and classified as cardiovascular problems included fainting, elevated blood pressure, and chest pain, among others. The authors admitted that the number of problems was small, and the participants were already more likely to have cardiovascular disease. The authors therefore cautioned **against** generalizing the events in the study to other populations, and they admitted that the differences between the TRT group and the non-TRT group "may have been due to chance alone." A study that confesses that its results cannot be distinguished from random chance does not show causation.

The other two studies are, as one expert recently put it, “so flawed that they represent non-science, or its close cousin, nonsense.”²² The *JAMA* study, like the *NEJM* study, involved men that were already sick; in fact they were selected **because** they had undergone coronary angiography. Half were diabetic, and over 80 percent had coronary heart disease. They were not selected for TRT randomly, as they would have been in a clinical trial. And it is unknown how much testosterone therapy actually made its way into their bodies, because the study assumed without evidence that once testosterone was prescribed, it was used continuously thereafter, and because 40 percent of the patients never had their testosterone checked after beginning treatment. Nor was the form of therapy used in the study the same as the one at issue in the complaints: only 13 patients used a testosterone gel, and the study did not report whether any of them had a problem. And the study suffered from blatant flaws, such as including 100 women in a study about men.

What’s more, the **actual** rate of cardiovascular problems was twice as high in the non-TRT group. Only after the authors used complex statistical adjustments to “interpret” the data was a higher rate detected in the TRT group. And using the study’s 95 percent confidence interval, it still remained possible that the **non**-TRT group had a higher rate of problems.

Finally, the *PLoS One* study failed to compare TRT users to non-TRT users, instead comparing them to users of an entirely different class of drugs designed for different medical issues and accompanied by different cardiovascular effects. In other words, the study failed to isolate the effect, if any, of using TRTs compared to using none. The researchers had no information about the heart attacks. They also had no information about other important risk factors for cardiovascular problems, such as diabetes, smoking, and obesity. The study did not look at strokes, blood clots, or deaths. And on its only subject, non-fatal heart attacks, it found **no**

²² *Androgen Study Group Urges FDA to Deny Public Citizen’s Petition to Add Black Box Warning to Testosterone Products* (May 14, 2014), <http://www.prnewswire.com/news-releases/androgen-study-group-urges-fda-to-deny-public-citizens-petition-to-add-black-box-warning-to-testosterone-products-259203831.html>.

increased risk in patients under 65 without a history of heart disease. Even the limited finding of increased risk in men over 65 or men with prior heart disease was undermined by the authors' admission that they could not determine whether the excess risk was related to the starting low level of testosterone in the body.

These three flawed studies cannot carry the plaintiffs' burden of plausibly alleging that TRTs cause heart attacks, strokes, blood clots, and related problems. The flaws and admissions reported above are not technical or minor; they are serious and important, and they do not permit a fair conclusion to be drawn that TRTs cause the problems that plaintiffs allege. For this reason alone, all of the complaints should be dismissed.

b. Specific causation

The complaints also fail in three independent ways to allege specific causation. Each reason alone is sufficient to show that the complaints should be dismissed.

The first reason relates to the three studies. Even if taken at face value despite their obvious flaws and admitted shortcomings, they still could not help these Plaintiffs allege that testosterone gels caused their medical problems, because Plaintiffs do not fit within the studies' parameters. The Plaintiffs do not fall within the same age groups as the men in the studies, do not allege the same preexisting medical conditions, do not allege the same risk factors, and do not allege they suffer from the same medical problems. The studies therefore cannot support an allegation that any Plaintiff's injuries were actually caused by TRTs.

The *NEJM* study was limited to men aged 65 and over (with an average age of 74) with severe mobility problems. No Plaintiff falls in that group. No Plaintiff alleged any mobility problems, and the only Plaintiff aged 65 or over, Cataudella, alleged that he had a "healthy and proactive lifestyle" (Cataudella Compl. ¶ 56), which is not a description of someone with severe mobility problems. *NEJM* participants also had a high prevalence of heart disease, high blood pressure, diabetes, obesity, and other risk factors, which no Plaintiff alleges. The *NEJM* study is of no use to any Plaintiff.

The *JAMA* study was limited to male veterans who underwent coronary angiography. No Plaintiff falls in that group. And over 80 percent in the study had coronary heart disease, unlike Plaintiffs, who allege “no history” of cardiovascular problems. In addition, every Plaintiff used testosterone gel, which was used by only 13 patients in the study—and the study did not link gels to even a single medical problem. The *JAMA* study helps no Plaintiff.

The *PLoS One* study looked only at non-fatal heart attacks, so it is irrelevant to any deceased Plaintiff or to anyone alleging a stroke or related problem. And its results showed an increased risk of non-fatal heart attack only in men age 65 or older and in men under 65 with prior heart disease. No Plaintiff who alleges a heart attack is 65 or older, or alleges prior heart disease. So the *PLoS One* study is just as unhelpful to Plaintiffs as the other two studies.

The second independent reason that each Plaintiff fails to plausibly allege specific causation is because, as this Court knows from “its judicial experience and common sense,” *Iqbal*, 556 U.S. at 679, the medical problems alleged in these cases are very common in men, and they are strongly associated with a wide variety of common risk factors.

Heart disease is the number 1 cause of death in the United States.²³ Some variety of it (such as myocardial infarction (heart attack), coronary heart disease, and heart failure) is alleged by 16 of these 39 plaintiffs. There are numerous major risk factors for heart disease: conditions inside the body (blood cholesterol levels, blood pressure, blood sugar), behavior (tobacco use, poor diet, physical inactivity, obesity, alcohol use), and heredity (genetic factors, family history).²⁴ All of those and more are serious alternative causes for alleged heart problems.

Stroke, some variety of which is alleged by 9 of these 39 Plaintiffs, is another leading cause of death, fourth in the United States.²⁵ It has numerous major risk factors: conditions inside

²³ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Leading Causes of Death* (Dec. 30, 2013), <http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>.

²⁴ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Heart Disease Risk Factors* (Oct. 26, 2009), http://www.cdc.gov/heartdisease/risk_factors.htm.

²⁵ *Leading Causes of Death*, *supra*.

the body (a prior stroke or mini-stroke, blood pressure, cholesterol levels, heart disease, blood sugar, sickle cell disease), behavior (poor diet, physical inactivity, obesity, alcohol use, tobacco use), and heredity (genetics, family history, age (which is the “single most important risk factor for stroke[s],” as they are more common in older people), sex (strokes are more common in men), and race/ethnicity).²⁶ Again, these are all alternative causes for the alleged strokes and related problems.

The third category of medical problems mentioned in these cases is blood clots, such as deep vein thrombosis and pulmonary embolism, which 14 of the 39 Plaintiffs allege. Blood clots are responsible for the deaths of an estimated 60,000 to 100,000 Americans each year, and occur without fatality in far more people: over half a million hospital stays in the U.S. each year include a blood clot diagnosis.²⁷ There are many important risk factors for blood clots, including: injury to a vein (from a muscle injury or surgery), slow blood flow (including from sitting for a long time), increased estrogen, chronic medical illnesses (such as heart disease, lung disease, and cancer), family history of blood clots, age (risk increases with age), obesity, and so on.²⁸

Contrary to *Twombly* and *Dura* and the other cases discussed above, the complaints do nothing to address any of these other factors besides the allegations by some (but not all) Plaintiffs about their ages and lack of prior cardiovascular problems. No complaint makes any allegations attempting to rule out the serious known risk factors as potential causes of their alleged conditions, such as obesity, diabetes, tobacco or alcohol use, high cholesterol, physical inactivity, family history of heart problems, and so on. The complaints make no attempt at all to

²⁶ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Stroke Risk Factors* (Mar. 17, 2014), http://www.cdc.gov/stroke/risk_factors.htm.

²⁷ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) – Blood Clot Forming in a Vein: Facts* (Sept. 25, 2012), <http://www.cdc.gov/ncbddd/dvt/data.html>; CENTERS FOR DISEASE CONTROL AND PREVENTION, *Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) – Blood Clot Forming in a Vein: Key Findings* (June 19, 2013), <http://www.cdc.gov/ncbddd/dvt/keyfindings.html>.

²⁸ *Pulmonary Blood Clot Forming in a Vein: Facts*, *supra*.

address the serious known risk factors as potential causes of the Plaintiffs' alleged medical problems.

The third independent failure to allege specific causation arises because the complaints allege almost nothing about Plaintiffs' use of testosterone gels, beyond the name of the gels themselves. No Plaintiff alleges what symptoms he had that led to his TRT treatment, what doctor(s) he visited, what test(s) the doctor conducted, and what result(s) were reported, whether the Plaintiff was diagnosed with hypogonadism, what dose of testosterone gel was prescribed, how often and for what duration it was used, what effect it had on the Plaintiff's testosterone and hematocrit levels as reported in follow-up tests, when the alleged medical problem occurred, and what the Plaintiff learned from his doctor about potential causes of his medical problems.

Without factual allegations about his use of testosterone gel, and without factual allegations about his other risk factors for the medical problem he alleges, no Plaintiff has given this Court plausible reason to believe that a testosterone gel actually caused his medical problem. The simple formula, used by each Plaintiff, of alleging that he used testosterone gel and later suffered a medical problem, is not nearly enough. The complaints should all be dismissed.

B. All causes of action based on a failure to warn should be dismissed.

Consumers cannot obtain prescription medication directly from the company that sells it. Instead, medications are prescribed by doctors who have a professional responsibility to make an individualized judgment, grounded in medical training and experience, about what treatment is best for that patient and whether the benefits of the drug outweigh its risks for the patient. That is why the near-universal rule is that a drug company's duty to warn is a duty *not* to the patients, but to their prescribing doctors. RESTATEMENT (THIRD) TORTS: PROD. LIAB. § 6 cmt. d (1998). "The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy." *Id.* cmt. b.

The learned intermediary doctrine is black-letter law in nearly every state. *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806-09 (E.D. Tex. 2002) (the doctrine is

followed in “48 states, the District of Columbia, and Puerto Rico”).²⁹ Among the states at issue in this motion, only Rhode Island, the home of Plaintiff Emmons, has not addressed the doctrine directly, but the Second Circuit has concluded that the Rhode Island Supreme Court would likely adopt it. *Greaves v. Eli Lilly*, 503 F. App’x. 70, 72 (2d Cir. 2012) (dismissing failure to warn claims); cf. *Hodges v. Brannon*, 707 A.2d 1225, 1227–28 (R.I. 1998) (implicitly recognizing that the duty to warn is a duty to warn the doctor).

Each Plaintiff claims that Defendants are liable for failing “to provide an adequate warning to consumers and/or their health care providers of the product.” Marino Compl. ¶ 60. Each Plaintiff also alleges that Defendants were negligent in failing to “warn of the risks and dangers” of TRTs. *Id.* ¶¶ 63-64. The learned intermediary doctrine governs all claims that are based on a failure to warn. *Centocor v. Hamilton*, 372 S.W.3d 140, 158-59 n.17 (Tex. 2012) (collecting cases); *Buckner v. Allergan Pharms.*, 400 So.2d 820, 822 (Fla. Dist. Ct. App. 1981); *Savina v. Sterling Drug*, 795 P.2d 915, 928 (Kan. 1990). Here, that includes each Plaintiff’s strict liability – failure to warn count and the failure to warn component of each Plaintiff’s negligence count. It also includes each Plaintiff’s claims for fraud and negligent misrepresentation because they rely on alleged “concealment” of facts regarding TRTs. Marino Compl. ¶¶ 78, 80, 87.

Plaintiffs’ failure to warn claims fail for three independent reasons. First, although the only duty is to warn a doctor, Plaintiffs allege nothing about what materials their doctors received and reviewed, why they were insufficient, what warning should have been provided, and why that warning would have prevented his own doctor from prescribing the drug. Second, the Defendants’ TRT prescribing information already warns that an increase in hematocrit may increase the risk of thromboembolic events, so Plaintiffs who allegedly suffered those injuries cannot assert a claim based on a failure to warn. Exs. 4, 5. Third, the sole Plaintiff over age 65 cannot maintain his claims based on a failure to warn, because the prescribing information for

²⁹ Additional case law at Appendix B.

Defendants' TRT already warns that there is insufficient long-term safety data in patients aged 65 and older.

1. Plaintiffs fail to allege any facts to state a plausible claim that warnings to doctors were inadequate.

Plaintiffs' failure-to-warn allegations focus exclusively on consumer advertisements regarding AndroGel—although few Plaintiffs claim to have actually seen and relied on those advertisements. Marino, for example, alleges: "In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that AbbVie adequately tested AndroGel for all likely side effects." Marino Compl. ¶ 53.

The duty to warn, however, is a duty to warn the doctors, not Plaintiffs. Only those warnings are relevant to a failure-to-warn claim. "Pharmaceutical companies ... in selling prescription drugs are required to warn *only* the prescribing physician who acts as a learned intermediary between manufacturer and consumer." *Walker v. Merck*, 648 F. Supp. 931, 934 (M.D. Ga. 1986) (emphasis added), *aff'd*, 831 F.2d 1069 (11th Cir. 1987). To state a plausible claim, each Plaintiff is required to allege the warnings his doctor reviewed; why those warnings were deficient; and what alternative warning should have been provided that would have prevented the doctor from prescribing the drug. *Bergstresser v. Bristol-Myers Squibb*, 2013 WL 1760525, at *5 (M.D. Pa.). Each Plaintiff must also plead that the lack of a warning caused his injury. *Motus v. Pfizer*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd* 358 F.3d 659 (9th Cir. 2004). Cases simply alleging that a pharmaceutical company should have warned the public about a drug, must be dismissed. *King v. Pfizer*, 2011 WL 3157305, at *3 (D. Md.).

Here, no Plaintiff addresses the warnings provided to doctors, let alone points to any deficiency in the prescribing information. *Bailey v. Janssen Pharmaceutica*, 288 F. App'x. 597, 608-09 (11th Cir. 2008). Each Plaintiff also fails to allege what the prescribing information should have said, and how that additional or alternative warning would have prevented their own doctors from prescribing them TRT or that the inadequate warning was otherwise a proximate

cause of their injuries. *Id.*; see also *Gonzalez v. Bayer Healthcare Pharms.*, 930 F. Supp. 2d 808, 814 (S.D. Tex. 2013) (dismissing failure-to-warn claim for lack of facts showing that warnings were inadequate or that the inadequacy caused injuries); *Tillman v. Taro Pharm. Indus. Ltd.*, 2011 WL 3704762, at *4, 8 (N.D. Ill. Aug. 17, 2011) (dismissing a failure-to-warn claim against a pharmaceutical manufacturer since the plaintiff “includes only formulaic recitations of the elements of her cause of action”). Plaintiffs’ claims based on failure to warn should be dismissed.

2. The TRT prescribing information already warns that an increase in red blood cell mass may increase the risk of thromboembolic events.

Plaintiffs who allegedly suffered blood clots, such as deep vein thrombosis, or pulmonary embolism (*see* Appendix A) cannot state a plausible claim based on failure to warn, because the TRT prescribing information already warns of these risks. Courts across the country have held that when a warning “specifically mentions the circumstances complained of, the warning is adequate of a matter of law.” *Gonzalez*, 930 F. Supp. 2d at 814.³⁰

Here, as explained above, the FDA-approved prescribing information informed doctors of the risk of thromboembolic events, which are blood clots, and include deep vein thrombosis and pulmonary embolism. Ex. 4 § 5.3. The AndroGel label, for example, warns that “[i]ncreases in hematocrit, reflective of increases in red blood cell mass, may require lowering or discontinuation of testosterone” because an “increase in red blood cell mass may increase the risk of thromboembolic events.” *Id.* Physicians are therefore advised to test hematocrit before

³⁰ See also *Salvio*, 2012 WL 517446, at *4-5 (“[w]arnings that advise physicians of the specific risks at issue are adequate as a matter of law”); *Moore v. Watson Pharm. Labs*, 2002 WL 63592, at *1-2 (E.D. Pa.) (granting motion to dismiss, based on learned intermediary doctrine, because the Physician’s Desk Reference warned about injuries); *King*, 2011 WL 3157305 (granting motion to dismiss, because plaintiffs’ physician was informed of the risks and side effects of taking Lipitor); *Rounds v. Genzyme*, 2011 WL 3925353, at *1 (11th Cir.) (affirming dismissal because a package insert warned about the alleged injuries); *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) (“the manufacturer’s duty to warn is ordinarily satisfied if a proper warning is given to the prescribing physician”); *Brumley v. Pfizer*, 149 F. Supp. 2d 305, 309-10 (S.D. Tex. 2001) (where “a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law”).

prescribing AndroGel, at three to six months, and annually thereafter. *Id.* “If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable concentration.” *Id.* The prescribing information also advises physicians that in clinical trials for AndroGel, one patient “reported [a] serious adverse event[] considered possibly related to treatment: deep vein thrombosis,” which is a type of blood clot. *Id.* § 6.1. *See* Ex. 5 for the other Defendants’ prescribing information.

This case is remarkably similar to *Reed v. Pfizer*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012). There, the plaintiff alleged that she suffered from deep vein thrombosis, pulmonary embolism, vein and tissue damage, and other injuries as a result of taking a birth control pill. *Id.* at 575. She pleaded nothing about the drug’s FDA-approved labels, which warned of those potential risks. *Id.* The court held that she fell “short of stating a failure to warn claim because the amended complaint does not allege facts identifying how the provided warnings were inadequate.” *Id.* at 576. The court observed that plaintiffs’ “assertions that warnings were not ‘adequate’ or ‘sufficient’ are nothing more than legal conclusions unsupported by factual content.” *Id.* “Plaintiffs have alleged factual content sufficient only to make plausible that Ms. Reed ingested [the drug] and thereafter suffered serious harm. If such allegations were sufficient to state a failure to warn claim, then anyone experiencing harm after using a product where the harm is a warned-of risk could successfully plead a claim.” *Id.* at 577; *see also Miller v. Pfizer*, 2014 WL 2155020, at *3-4 (N.D. Ala.) (dismissing complaint because plaintiff did not state how the drug’s warnings were inadequate).

Plaintiffs’ physicians, already on notice that TRTs carry a potential risk of blood clots, decided to prescribe the drug anyway, making a medical determination that the potential benefit of the drug outweighed any potential negative consequences. None of the complaints refer to the prescribing information or even suggest that those materials were inadequate. With the warning having already been given and considered, all claims that are based on a failure to warn about blood clots such as deep vein thrombosis and pulmonary embolisms should be dismissed.

In addition, none of the Plaintiffs who allege they suffered a heart attack or stroke pleaded that those injuries were caused by anything other than a blood clot. Some blood clots “can cause heart attack or stroke.”³¹ No Plaintiff pleads that their heart attack or stroke was caused by anything other than a blood clot, so the failure to warn claims asserted by Plaintiffs alleging heart attack or stroke should be dismissed as well, for failure to plead that their problems were not caused by a blood clot.

3. The prescribing information already warns about the use of TRTs by persons aged 65 and over.

Finally, AndroGel’s prescribing information warns that “there is insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease.” Ex. 4 § 6.1. *See* Ex. 5 for the other Defendants’ prescribing information. The sole Plaintiff age 65 or over, Cataudella, was 74 when he first began taking TRTs. His alleged injury is pulmonary embolism, so his claims should be dismissed, as explained above, because pulmonary embolism is already the subject of a warning.

His claims should also be dismissed because the prescribing information warns about the lack of sufficient long-term safety data for older patients like him. Cataudella never alleges that this warning was false (in other words, that there truly was sufficient long-term safety data), what warning the prescribing information should have given in the absence of actual data on that subject, how the additional information would have prevented his doctor from prescribing AndroGel, and how the inadequate warning caused his injury. His claims should be dismissed.

C. Plaintiffs’ claims alleging express warranty should be dismissed.

No Plaintiff identifies any specific express warranty that was breached. Instead, they claim that TRTs were marketed in general as “safe, effective, fit and proper for [their] intended use[s].” That does not suffice. “In order to plead a cause of action for breach of express warranty, one must allege the exact terms of the warranty” that was actually given by the defendant. *Williams v. Beechnut Nutrition*, 185 Cal. App. 3d 135, 142 (2d Dist. 1986); *see also Tillman*,

³¹ *Blood Clot Forming in a Vein: Facts, supra*.

2011 WL 3704762, at *8 (N.D. Ill.) (dismissing for failure to allege a specific express warranty about a drug, and reliance on it). (Other cases are collected at Appendix C.) A simple claim that a drug was promoted as “safe and effective” fails as a “naked assertion” that is “devoid of further factual enhancement.” *McCauley v. Hospira*, 2011 WL 3439145, at *6 (M.D.N.C.). Plaintiffs’ express warranty claims should be dismissed.

D. Plaintiffs’ claims alleging breach of implied warranty should be dismissed.

Plaintiffs also assert claims for breach of the implied warranty of merchantability, alleging that TRT medications were “neither safe for [their] intended use nor of merchantable quality.” Marino Compl. ¶ 71. These allegations, repeated almost word-for-word in all of the complaints, fail to state any claim because plaintiffs have not pleaded facts to allege plausibly that any implied warranty was breached.³² *Iqbal*, 556 U.S. at 678.

For example, the complaints do not allege that TRTs failed to work as indicated. There is no allegation that TRTs failed to raise a particular Plaintiff’s testosterone levels. *Tillman*, 2011 WL 3704762, at *8 (dismissing for failure “to specify for what purpose she consumed [the drug]” and its failure to perform); *Wendell v. Johnson & Johnson*, 2010 WL 271423, at *5 (N.D. Cal.) (dismissing for failure to allege a drug was unfit for its indicated use as an anti-inflammatory); *see also Kwasniewski*, 2013 WL 2558283, at *2 (dismissing implied warranty claim for failing to plead causation sufficiently). Accordingly, Plaintiffs’ implied warranty claims must be dismissed.

II. All claims sounding in fraud should be dismissed under Rule 9(b).

Each Plaintiff vaguely and broadly alleges that the Defendants committed fraud because they “willfully deceived” Plaintiffs by “concealing” the “true facts” about TRT. Plaintiffs assert without any detail that Defendants somehow knew that TRT is not “safe, fit and effective.” Yet Plaintiffs provide none of the required particularity regarding the supposed “fraud” that they are claiming. Under Rule 9(b), Plaintiffs’ claims sounding in fraud should be dismissed.

³² In addition, as detailed in Section III, some states have altogether eliminated implied warranty claims in the context of pharmaceutical product liability litigation.

A. Claims sounding in fraud must be pleaded with particularity.

Rule 9(b) requires claims sounding in fraud to be pleaded with particularity. *Borsellino v. Goldman Sachs Grp.*, 477 F.3d 502, 507 (7th Cir. 2007). That rule serves “three main purposes: (1) protecting a defendant’s reputation from harm; (2) minimizing ‘strike suits’ and ‘fishing expeditions’; and (3) providing notice of the claim to the adverse party.” *Vicom v. Harbridge Merch. Servs.*, 20 F.3d 771, 777 (7th Cir. 1994) (citations omitted). “Accusations of fraud can do serious damage to the goodwill of a business firm or a professional person. People should be discouraged from tossing such accusations into complaints in order to induce advantageous settlements or for other ulterior purposes. Rule 9(b) does that.” *Bankers Trust v. Old Republic Ins.*, 959 F.2d 677, 683 (7th Cir. 1992).

Under Rule 9(b), a plaintiff must “state with particularity the circumstances constituting fraud,” including specifically identifying the “identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff.” *Gen. Elec. Cap. Corp.*, 128 F. 3d at 1078. Conclusory allegations that a defendant’s conduct was fraudulent and deceptive do not satisfy the rule. *Butler v. Greenlee Textron*, 2011 WL 1258108, at *2 (S.D. Ill.). Where fraud claims are based on omissions or concealment, the plaintiff must plead the particulars of the omission and fraudulent concealment—what was concealed, who concealed it, when it was concealed, how it was concealed, and how he or she acted in reliance on the omission or concealment. *Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 469-71 (7th Cir. 1999); *Crichton v. Golden Rule Ins.*, 2006 WL 2349961, at *4 (S.D. Ill.).

In these cases, the counts subject to Rule 9(b) are labeled as fraud, fraud by concealment, fraudulent misrepresentation, fraud and deceit, and negligent misrepresentation. The last of those is equally subject to Rule 9(b), even though the claim does not contain the word “fraud,” because the negligent misrepresentation claims rely on the exact same (unspecified) misrepresentations as the fraud claim, and all contain allegations that the Defendants acted to “willfully deceive” Plaintiffs and with “the intention” to induce reliance. Marino Compl. ¶¶ 83-84. In other words,

the negligent misrepresentation claims sound in fraud and must be stated with particularity. *Borsellino*, 477 F. 3d at 507; *Rosenstern v. Allergan*, — F. Supp. 2d —, 2013 WL 5782382, at *7 (N.D. Ill.) (negligent misrepresentation claim sounded in fraud because “Plaintiff does not allege that [defendant] acted with ‘carelessness or negligence in ascertaining the truth’ ..., but rather that [defendant] knowingly made false statements”).

B. Plaintiffs’ claims sounding in fraud are deficient.

Plaintiffs fail to plead the substance of any specific false representation, concealment or omission of fact, how they relied on those facts, the timing, the person involved, or any of the other concrete details that Rule 9(b) requires. Instead, Plaintiffs offer vague, generalized statements that the “true facts” regarding AndroGel were concealed and/or misrepresented. Plaintiffs’ fraud allegations are virtually identical. As an example, the Marino Complaint alleges:

78. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroGel, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff’s physicians and the general public, the true facts concerning AndroGel, which the Defendants had a duty to disclose.

79. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff’s physicians and the general public as to the benefits, health risks and consequences of using AndroGel. Defendants knew of the foregoing, that AndroGel is not safe, fit and effective for human consumption, that using AndroGel is hazardous to health, and that AndroGel has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

80. Defendants concealed and suppressed the true facts concerning AndroGel with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe AndroGel, and Plaintiff would not have used AndroGel, if they were aware of the true facts concerning its dangers.

These allegations, repeated in complaint after complaint after complaint, are entirely generic and boilerplate. They contain no suggestion of an actual fraud carried out at a specific time by real people using meaningfully deceptive statements or omissions that a plaintiff actually saw and relied on and as a result was injured. A mere listing of the alleged “dangers of the treatment” coupled with a “bare claim” that they were concealed and omitted does not plead

fraud with the required particularity. *Koch v. I-Flow*, 715 F. Supp. 2d 297, 303 (D.R.I. 2010).³³ The required information might be complex, but the “necessity for complexity ... does not give litigants license to plead by means of obfuscation.” *Jennings v. Emry*, 910 F. 2d 1434, 1436 (7th Cir. 1990).

A few of the complaints are against multiple Defendants, alleging that a particular Plaintiff—Cataudella, Lau, and Parker—used more than one Defendant’s TRT. The fraud-based claims in those complaints fail for an additional reason under Rule 9(b): they lump Defendants together without specifying the role of any individual Defendant and without attributing any false statement to any Defendant in particular. This is completely inconsistent with Rule 9(b)’s requirement of particularized allegations. *Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990) (affirming the dismissal of a complaint that “lumps all the defendants together and does not specify who was involved in what activity”); *Design Time v. Synthetic Diamond Tech.*, 674 F. Supp. 1564, 1569 (N.D. Ind. 1987) (“A complaint that attributes misrepresentations to all defendants, ‘lumped’ together for pleading purposes, generally is insufficient.”). This pleading failure is especially glaring here, because Defendants are competitors. They have different employees, make different statements, use different advertisements, have different product

³³ See also *Rosenstern*, 2013 WL 5782382, at *7 (dismissing fraud allegations because plaintiff “has not alleged with particularity what promotional materials contained false statements ... what individuals made those statements to Rosenstern or her doctors, and when and where those statements occurred”); *Koch*, 715 F. Supp. 2d at 303-04 (dismissing allegations that false statements were made to “the public, the Plaintiff ..., her doctors, hospitals, healthcare professionals, and/or the FDA ... in reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media”); *Swanson v. Citibank*, 614 F.3d 400, 406 (7th Cir. 2010) (“plaintiff must plead actual damages arising from her reliance on a fraudulent statement”); *Hefferman v. Bass*, 467 F.3d 596, 601 (7th Cir. 2006) (“Rule 9(b) requires that facts such as ... ‘the method by which the misrepresentation was communicated to the plaintiff’ be alleged in detail”); *Morse v. Abbott Labs.*, 756 F. Supp. 1108, 1112 (N.D. Ill. 1991) (under Rule 9(b), the plaintiff “is required to allege actual reliance with particularity.”). *U.S. v. Lockheed-Martin*, 2002 WL 1794004, at *3 (N.D. Ill.) (dismissing allegations that failed “to connect allegedly false statements to specific claims ... [and] state intelligibly why each particular claim or statement is false”) (emphasis in original).

labels, and so on. All claims that sound in fraud against more than one Defendant should be dismissed.

III. State laws bar many of Plaintiffs' claims.

These cases all assert federal jurisdiction by diversity of citizenship, so state substantive law governs Plaintiffs' claims. *Gacek v. Am. Airlines*, 614 F.3d 298, 301-02 (7th Cir. 2010); *Tamburo v. Dworkin*, 601 F.3d 693, 700 (7th Cir. 2010). To determine which state's law applies, this Court uses the forum state's—Illinois's—choice of law analysis. *Klaxon v. Stentor Elec. Mfg.*, 313 U.S. 487, 496 (1941); *Hinc v. Lime-O-Sol*, 382 F.3d 716, 719 (7th Cir. 2004).

Illinois uses the most significant relationship test. Under that test, “[i]n an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship.” *Townsend v. Sears, Roebuck*, 879 N.E. 2d 893, 903-04 (Ill. 2007). Here, the alleged injuries occurred in each Plaintiff's home state. For that reason, each Plaintiff's home state's law governs his claims.

No other state has a more significant relationship to each Plaintiff's dispute. Each Plaintiff experienced low testosterone, was prescribed TRT, and used that therapy in his home state.³⁴ And if any Plaintiff viewed advertisements or websites related to TRTs, that also occurred in his home state. Thus, the substantive law of each Plaintiff's own home state governs his claims. *Id.* at 905.

The laws of many of the Plaintiffs' home states require dismissal of some or all of the claims in these cases, as set forth below.

³⁴ The Plaintiffs in only one case allege a connection more than one state. Blades and his wife currently reside in Maryland, but were living in Wyoming at the time of his injury. Given that Wyoming is the state where the injury occurred and Maryland is not alleged to have a more significant relationship, Wyoming law applies to their claims.

A. State product liability statutes bar many of Plaintiffs' claims.

Some states have statutes that limit the causes of action that a product liability plaintiff may bring, or statutes that bar those claims altogether.³⁵ This section explains the causes of action that should be dismissed pursuant to those statutes.

1. Michigan

Michigan law provides an “absolute defense” to *all* claims asserted against a drug manufacturer in a case alleging personal injury or death from any “fault in the standards, testing, warning, instruction, marketing, selling, advertising or labeling of the drug.” M.C.L. § 600.2946(5); *White v. SmithKline Beecham*, 538 F. Supp. 2d 1023, 1027-28 (W.D. Mich. 2008). The absolute defense applies so long as “(1) the FDA approved the safety and efficacy of the drug and (2) the drug and the labeling were in compliance with the FDA’s approval at the time the drug left control of the manufacturer, unless either the fraud or bribery exception applies.” *Id.* at 1027 (dismissing all claims); *see also Marsh v. Genentech*, 693 F.3d 546, 552 (6th Cir. 2012) (same); *Taylor v. SmithKline Beecham*, 658 N.W.2d 127, 131 (Mich. 2003) (same); *In re Baycol Prods. Litig.*, 2008 WL 8797727, at *11 (D. Minn. 2008) (same).

The claims of Plaintiff Montgomery, from Michigan, are subject to the absolute defense against all claims. That defense has a few limited exceptions, none that apply here. First, it does not apply if the drug was “sold ... in the [U.S.] after [an FDA] order to remove the drug from the market.” M.C.L. § 600.2946(5)(a)-(b). There is no order here. Second, it does not apply if the manufacturer “intentionally withheld or misrepresented to the FDA information concerning the drug” or made an “illegal payment to an official or employee of the FDA.” M.C.L. § 600.2946(5)(a)-(b). There is no allegation of fraud or bribery here, and in any event a mere allegation would not suffice; a plaintiff must “show that the FDA has made its own

³⁵ In addition to the states discussed in the text, other states such as New Jersey and Connecticut also have product liability statutes that limit or bar the claims of Plaintiffs from those states. Those statutes are not discussed in this motion because the Plaintiffs whose cases are subject to this motion do not reside in those other states. Some Plaintiffs with cases pending in this Court do, however, reside in those other states.

determinations of fraud or bribery.” *Ammend v. BioPort*, 2006 WL 1050509, at * 3 (W.D. Mich.). There is no FDA finding of fraud or bribery here. All claims under Michigan law must therefore be dismissed.

2. Texas

Texas law provides that any causes of action that are based on inadequate warnings or information, no matter how those causes of action are characterized, are consolidated into one inadequate warning cause of action governed by § 82.007 of the Texas Civil Practice and Remedies Code. Under that section, a drug manufacturer is not liable if the FDA-approved the “warnings and information” that accompanied the product. Similar to the law in Michigan, the bar against liability can be overcome only if (1) Defendant committed fraud on the FDA; (2) Defendant sold the product after FDA ordered it removed from the market; (3) Defendant promoted the product for an unapproved use and that use caused the injury; or (4) Defendant bribed an FDA official, causing the FDA approved warnings to be inadequate. *Gonzalez v. Bayer Healthcare Pharms.*, 930 F. Supp. 2d 808, 820 (S.D. Tex. 2013). The plaintiff must not merely allege fraud, but show that the FDA itself has found fraud. *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F. 3d 372, 380 (5th Cir. 2012). There is no finding, or even an allegation, that could support any of the exceptions in these cases.

Each of the six causes of action asserted by the Texas Plaintiff, Myers, is premised on a failure to warn or inadequate information. Myers Compl. ¶ 61 (strict liability: “failed to provide an adequate warning”), ¶ 64 (negligence: “failed to adequately test and warn of the risks”); ¶ 69 (breach of implied warranty: “Defendants impliedly warranted” that AndroGel is “safe and fit for the use for which it was intended”); ¶ 74 (breach of express warranty: “Defendants expressly represented and warranted” that AndroGel is “safe, effective, fit and proper for its intended use”); ¶ 80 (fraud: “Defendants concealed and suppressed the true facts regarding AndroGel”); ¶ 87 (negligent misrepresentation: “If Plaintiff had known of the true facts and the facts concealed

by the Defendants, Plaintiff would not have used AndroGel.”). Section 82.007 therefore bars all of Myers’s claims or any other claims under Texas law.³⁶

3. Kansas

Kansas law allows only one cause of action in a case alleging injury from a product: a strict liability claim under the Kansas Product Liability Act, Kan. Stat. § 60-3301 *et seq.* “[T]he purpose of the [KPLA] was ... to eliminate the complex pleading provided at common law.” *Gaumer v. Rossville Truck & Tractor*, 257 P.3d 292, 299 (Kan. 2011). Thus, all other causes of action in a personal injury product liability case, including causes of action for negligence, breach of express or implied warranty, fraud, and negligent misrepresentation, must be dismissed. *Mattos v. Eli Lilly*, 2012 WL 1893551, at *2 (D. Kan.) (barring claims for negligence, breach of express and implied warranty, misrepresentation by omission, and fraudulent misrepresentation); *Baughn v. Eli Lilly*, 356 F. Supp. 2d 1177, 1182-83 (D. Kan. 2005) (barring claims for negligence, breach of warranty and negligent misrepresentation).

Two Plaintiffs from Kansas, Cripe and Bartholic, assert the standard six causes of action: strict liability for failure to warn, negligence, breach of express and implied warranty, fraud, and negligent misrepresentation. Only their first cause of action, for strict liability, can stand under the KPLA. All other causes of action must be dismissed.

4. Indiana

a. Indiana Product Liability Act

Indiana law permits Plaintiff Dobbs to assert only a cause of action under the Indiana Product Liability Act, Ind. Stat. §§ 34-20-1-1 *et seq.*, when seeking to recover in tort from a

³⁶ Tex. Civ. Prac. & Rem. Code § 82.001(2) (listing strict liability and breach of warranty claims in the definition of products liability actions subject to dismissal); *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 977 (S.D. Tex. 2012) (dismissing strict liability, negligence and breach of warranty claims based on failure to warn where warnings were approved by FDA and plaintiff failed to allege grounds for rebutting statutory presumption); *Del Valle v. Pliva*, 2012 WL 4747259, at *1, 4 (S.D. Tex.) (finding plaintiff’s claims for misrepresentation and fraud were “all products liability claims [relating] to inadequate product warnings” and therefore afforded protection by the rebuttable presumption that the warnings were adequate).

product manufacturer or seller for a physical harm. *In re Inlow Accident Litig.*, 2002 WL 970403, at *12 (S.D. Ind.) (the IPLA is “applicable to all actions for physical harm brought by a consumer against a manufacturer or seller of a product, regardless of the substantive legal theory.”). The IPLA is a codification of the common law doctrine of strict liability, through which the Indiana legislature intended to preempt the field of product liability in tort. *Koske v. Townsend Eng’ing*, 551 N.E.2d 437, 442 (Ind. 1990). All other claims are subsumed by a single strict liability claim. *Cincinnati Ins. v. Hamilton Beach/Proctor-Silex*, 2006 WL 299064, at *2, 3 (N.D. Ind.).

b. Negligent Misrepresentation

Plaintiff Dobbs’s negligent misrepresentation claim must in any event be dismissed because Indiana has not extended that tort to product liability claims. In order to state a negligent misrepresentation claim under Indiana law, “there must be an employee of the Defendants negligently misrepresenting material facts to the Plaintiff in the context of a business transaction.” *Lautzenhiser v. Coloplast A/S*, 2012 WL 4530804, at *6 (S.D. Ind.). “[T]he tort has not been extended outside the business transaction context in Indiana.” *Id.* And “no Indiana case has extended negligent misrepresentation to cover concealment or omission.” *Id.* at *6. There is no such transaction in this case, and the tort cannot in any event cover alleged concealment, so Dobbs’s negligent misrepresentation claim must be dismissed.

5. Ohio

Ohio law, like Kansas and Indiana law, allows only a single cause of action in a product liability case, which must be asserted under the Ohio Products Liability Act, Ohio Rev. Code § 2307.71 *et seq.* The act bars all other claims based on injury from a product’s design, formulation, testing, marketing, lack of warning, or failure to conform to a representation or warranty. *Id.* § 2307.71(A)(13); *see also Delahunt v. Cytodyne Techs.*, 241 F. Supp. 2d 827, 842 (S.D. Ohio 2003). In short, the OPLA “abrogate[s] all common law product liability causes of action.” *Id.* § 2307.71(B). The three Ohio Plaintiffs assert the standard six causes of action. All

of those causes of action must be dismissed, and a single claim under the OPLA should take their place.³⁷

B. Many of Plaintiffs' other causes of action also fail under state law.

1. Pennsylvania

Pennsylvania law allows only one cause of action to be asserted against a pharmaceutical company for injuries alleged from prescription drugs. “[W]here the adequacy of warnings associated with prescription drugs is at issue,” as it is in these cases, “the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., *the manufacturer’s negligence, is the only recognized basis of liability.*” *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) (emphasis added).

Pennsylvania law therefore does not allow a claim for strict liability based on a failure to warn. Pennsylvania follows the Restatement (Second) of Torts § 402A, which holds that prescription drugs are “unavoidably unsafe products” on which no claim of strict liability from a failure to warn may be based. *Id.* at 889-91; *Doughtery v. C.R. Bard*, 2012 WL 2940727, at *6 (E.D. Pa.); *Tatum v. Takeda Pharms.*, 2012 WL 5182895, at *2 (E.D. Pa.); *Luke v. Am. Home Prods.*, 1998 WL 1781624, at *7 (C.P. Phila.); *Adams v. Wyeth*, 2005 WL 1528656, at *6 (C.P. Phila.) (“Pennsylvania courts have repeatedly declined to impose strict liability on prescription drug manufacturers.”). The claims by the Plaintiff from Pennsylvania, Kelly, for strict liability (count 1) should be dismissed.

Pennsylvania law also does not allow a claim for breach of express or implied warranty. “[S]ince the Pennsylvania Supreme Court’s ruling in *Hahn v. Richter*, Pennsylvania courts, as

³⁷ See, e.g., *Miles v. Raymond*, 612 F. Supp. 2d 913, 919-21 (N.D. Ohio 2009) (all common law product liability claims barred); *CCB v. Chemque*, 649 F. Supp. 2d 757, 763-64 (S.D. Ohio. 2009) (negligence claim barred); *Stratford v. SmithKline Beecham*, 2008 WL 2491965, at *7 (S.D. Ohio) (claims for breach of express warranty and implied warranty of merchantability barred); *Fulgenzi v. Pliva*, 867 F. Supp. 2d 966, 972-73 (N.D. Ohio 2012) (drug-related claims for fraud and misrepresentation barred), *rev’d on other grounds*, 711 F.3d 578 (6th Cir. 2013); *In re Heparin Prods. Liab. Litig.*, 2011 WL 3875361, at *2-3 (N.D. Ohio) (negligent misrepresentation claim barred); *Smith v. Smith & Nephew*, 2014 WL 934541, at *1 (S.D. Ohio) (dismissing breach of express warranty and negligence claims).

well as federal courts applying Pennsylvania law, have consistently held that negligence is the only theory upon which a prescription drug manufacturer can be held liable for failure to warn. Because *Hahn* requires that this Court dismiss all tort claims that do not rest on a theory of negligence, Plaintiff's express and implied warranty claims shall be dismissed." *Aaron v. Wyeth*, 2010 WL 653984, at *11 (W.D. Pa.).³⁸ Kelly's claims for breach of express and implied warranty (counts 3 and 4) should be dismissed.

2. Florida

The Plaintiff from Florida, Lau, asserts claims for breach of express and implied warranty. But Florida law does not allow warranty claims in personal injury cases where there is no privity (no direct contractual relationship between the plaintiff and defendant) and where a claim for strict liability is available. Fla. Stat. § 672.318; *Kramer v. Piper Aircraft*, 520 So. 2d 37, 39 (Fla. 1988). In other words, "the doctrine of strict liability in tort supplants" warranty claims. *Kramer*, 520 So. 2d at 39; *see also Guenther v. Novartis Pharm.*, 2013 WL 1498162, at *4 (M.D. Fla.) ("Under Florida law, a plaintiff must be in privity of contract to recover under theories of breach of express or implied warranties."); *Fields v. Mylan Pharm.*, 751 F. Supp. 2d 1257, 1259 (N.D. Fla. 2009) (dismissing claims for breach of implied warranty and express warranty because plaintiff failed to allege existence of contractual relationship with drug manufacturer); *Bailey v. Janssen Pharm.*, 2006 WL 3665417, at *5 (S.D. Fla.), *aff'd* 536 F.3d

³⁸ *See also Kline v. Pfizer*, 2008 WL 4787577, at *3 (E.D. Pa.) (dismissing non-negligence claims); *Salvio*, 810 F. Supp. 2d at 755–56 (dismissing negligence and breach of warranty claims); *Leonard v. Taro Pharms.*, 2010 WL 4961647, at *5 (W.D. Pa.) (dismissing express and implied warranty claims); *Luke*, 1998 WL 1781624, at *5–6 ("there is no cause of action for a breach of implied warranty in prescription drug cases involving drug manufacturers"); *Albertson v. Wyeth*, 2003 WL 21544488, 63 Pa. D. & C. 4th 514, 536 n.6 (C.P. Phila. 2003) ("prescription drugs are not covered by a warranty of fitness for ordinary purpose"); *Parkinson v. Guidant*, 315 F. Supp. 2d 741, 752–53 (W.D. Pa. 2004) ("Pennsylvania courts have held that the nature of prescription drugs precludes claims for breaches of implied warranty for similar reasons as comment K to § 402A precludes a finding that such drugs are 'unreasonably dangerous'"); *Doughtery*, 2012 WL 2940727, at *7 (Pennsylvania law "precludes implied-warranty claims against manufacturers of prescription drugs and devices to the same extent that it precludes strict liability claims against such manufacturers").

1202 (11th Cir. 2008) (same). There is no privity here—Defendants do not sell prescription drugs directly to consumers—and Lau is asserting a strict liability claim (count 1). Lau’s express and implied warranty claims (counts 3 and 4) should be dismissed.

3. Massachusetts

The Massachusetts Plaintiff, O’Donnell, asserts a claim for strict liability. But the separate tort of strict liability does not exist under Massachusetts law. “[T]here is no independent claim of strict liability in tort under Massachusetts law, and the sole remedy for strict liability is provided under the UCC.” *Cruickshank v. Clean Seas*, 346 B.R. 571, 578 (D. Mass. 2006)); *see also Mason v. Gen. Motors*, 490 N.E.2d 437, 442 (Mass. 1986); *Swartz v. Gen. Motors*, 378 N.E.2d 61, 62 (Mass. 1978). “In Massachusetts, ‘there is no strict liability in tort apart from liability for breach of warranty under the Uniform Commercial Code, G.L. c. 106, §§ 2–314–2–318.’” *Guzman v. MRM/Elgin*, 567 N.E.2d 929, 932 (Mass. 1991) (quoting *Swartz*, 378 N.E.2d at 62). Instead, “Massachusetts law of warranty is congruent in nearly all respects” with a strict liability theory of recovery. *Id.* The Supreme Judicial Court has specifically refused to hold “that, apart from liability for breach of warranty under our statute, there may be liability without fault for defective products.” *Mason*, 490 N.E.2d at 442. O’Donnell’s strict liability claim (count 1) should therefore be dismissed.

4. Minnesota

Minnesota law is essentially opposite to the law in Massachusetts. Under Minnesota law, a personal injury plaintiff’s claim for strict liability preempts any claim for breach of implied warranty claims. *Forslund v. Stryker*, 2010 WL 3905854, at *7-8 (D. Minn.) (dismissing implied warranty claim); *Nimeth v. Prest Equip.*, 1993 WL 328767, at *1 (Minn. Ct. App.) (same); *Goblirsch v. Western Land Roller*, 246 N.W.2d 687, 690 (Minn. 1976) (implied warranty claim is “redundant” of strict liability); *Kapps v. Biosense Webster*, 813 F. Supp. 2d 1128, 1162 (D. Minn. 2011) (same). “In other words, strict liability in tort removes from consideration contract rules when in fact no contract exists.” *Farr v. Armstrong Rubber*, 179 N.W.2d 64, 71 (Minn. 1970). “[R]ules defining and governing warranties that were developed to meet the needs of

commercial transactions cannot properly be invoked to govern the manufacturer's liability to those injured by its defective products unless those rules also serve the purposes for which such liability is imposed.” *Id.* (quoting *Greenman v. Yuba Power Prods.*, 377 P.2d 897, 901 (Cal. 1963)). Given that the Plaintiff from Minnesota, Hughes, alleges a strict liability claim, his claim for breach of implied warranty (count 3) should be dismissed.

5. Arizona

The sole Arizona Plaintiff, Cataudella, improperly asserts in his complaint claims for both strict liability—failure to warn (count 1) and breach of implied warranty (count 3). “[I]n Arizona, when a complaint alleges product liability claims under theories of both breach of implied warranties and strict liability, those theories merge: ‘the theory of liability under implied warranty has been merged into the doctrine of strict liability in tort, so that it is on this latter doctrine that the plaintiff’s claims must stand or fall.’” *Hearn v. R.J. Reynolds Tobacco*, 279 F. Supp. 2d 1096, 1103 (D. Ariz. 2003) (quoting *Scheller v. Wilson Certified Foods, Inc.*, 559 P.2d 1074, 1076 (Ariz. Ct. App. 1977)). The Court should dismiss Cataudella’s breach of implied warranty claim (count 3). *Botha v. Wright Medical Tech.*, 2012 WL 2675266, at *4 (D. Ariz.); *Mills v. Bristol-Myers Squibb*, 2011 WL 4708850, at *4 (D. Ariz.).

6. North Carolina

Under North Carolina law, “[t]here shall be no strict liability in tort in product liability actions.” N.C. Gen. Stat. §§ 99B-1.1; *see also Smith v. Fiber Controls Corp.*, 268 S.E.2d 504, 509-10 (N.C. 1980) (refusing to adopt the rule of strict liability in product liability cases); *Seese v. Volkswagenwerk*, 648 F.2d 833, 837-38 (3d Cir. 1981) (same); *Stoddard v. Wyeth*, 630 F. Supp. 2d 631, 632 (E.D.N.C. 2009) (same); *Byrd Motor Lines v. Dunlop Tire*, 304 S.E.2d 773, 778 (N.C. App. Ct. 1983) (same). The strict liability claim (count 1) asserted by Plaintiffs Gibby and Lewis should be dismissed.

7. Oregon

a. Express and implied warranty claims

Oregon Revised Statute § 72.6070(3) states when a tender of goods has been accepted, “[t]he buyer must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.” That notice requirement applies in warranty actions “for personal injuries resulting from the purchase of a consumer product,” including an action against a drug maker. *Allen v. G.D. Searle*, 708 F. Supp. 1142, 1159 (D. Or. 1989). Filing a lawsuit does *not* constitute proper notice. *Parkinson v. Novartis Pharms.*, 2014 WL 1098123, at *11 (D. Or.).

The Plaintiff from Oregon, King, asserts express and implied warranty claims (counts 3 and 4) without alleging that he gave proper notice, and Defendants are not aware of any notice having been given. Those claims should be dismissed.

b. Negligent misrepresentation

King’s negligent misrepresentation claim should also be dismissed because he fails to allege any facts that Defendants owed him any duty “beyond the common law duty to exercise reasonable care.” *Gillman v. Boston Sci.*, 2012 WL 892239, at *4 (D. Or.). Oregon law bars negligent misrepresentation claims unless there is a special relationship in which “one party has authorized the other to exercise independent judgment in his or her behalf and, consequently, the party who owes the duty has a special responsibility to administer, oversee, or otherwise take care of certain affairs belonging to the other party.” *Id.* “Examples of special relationships include attorney-client, patient-physician, principal-agent, and trustee-beneficiary relationships.” *Id.* King does not and cannot allege a special relationship with Defendants. His negligent misrepresentation claim (count 6) should be dismissed.

8. Nevada

Like Indiana law, “Nevada has expressly rejected the tort [of negligent misrepresentation] ... where [p]laintiff seeks recovery for personal injuries.” *Moretti v. Wyeth*, 2009 WL 749532, at *3 (D. Nev.). The negligent misrepresentation tort “is only available to those suffering pecuniary

injury in the context of a business transaction.” *Forest v. E.I. Du Pont de Nemours*, 791 F. Supp. 1460, 1470 (D. Nev. 1992); *see also Scaffidi v. United Nissan*, 425 F. Supp. 2d 1159, 1170 (D. Nev. 2005); *Barmettler v. Reno Air*, 956 P.2d 1382, 1387 (Nev. 1998). The claim by the Plaintiff from Nevada, Parker, for personal injury arising out of negligent misrepresentation (count 6), should be dismissed.

9. Colorado

In the only case involving a Colorado Plaintiff, Darby, the wife asserts her own claim for negligent infliction of emotional distress. Under Colorado law, this claim requires allegations that the defendant caused the plaintiff to fear for *her own* safety. *Draper v. DeFrenchi-Gordineer*, 282 P.3d 489, 496-97 (Colo. App. 2011). The plaintiff must show that she suffered physical injury or was in the “zone of danger.” *Id.* at 497. “If the plaintiff has observed injury to a family member but was in no danger herself, there can be no recovery.” *Id.* (quoting *Colwell v. Mentzer Inv.*, 973 P.2d 631, 638 (Colo. App. 1998)). That is exactly the claim here. The wife does not allege that she suffered any physical injury, that she was in the zone of danger, or that she feared for her own safety. Her claim (count 13) should be dismissed.

The *Darby* complaint also includes causes of action for strict liability for design defect (Count 1), manufacturing defect (Count 3), and failure to test (Count 4). The complaint does not state any facts to support these counts. *Ashcroft*, 129 S. Ct. at 1949 (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.”).

A design defect claim requires consideration of multiple factors, none of which are alleged in the Complaint. *Barton v. Adams Rental*, 938 P.2d 532, 537 (Colo. 1997).³⁹ Regarding

³⁹ These include: (1) the usefulness and desirability of the product—its utility to the user and to the public as a whole; (2) the safety aspects of the product—the likelihood that it will cause injury and the probable seriousness of the injury; (3) the availability of a substitute product which would meet the same need and not be as unsafe; (4) the manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility; (5) the user’s ability to avoid danger by the exercise of care in the use of the product; (6) the user’s anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and (7) the feasibility, on the part of the

the manufacturing defect claim, “[t]he question ... is whether the product as produced conformed with the manufacturer’s specifications.” *Camacho v. Honda Motor*, 741 P.2d 1240, 1247 (Colo. 1987). The complaint fails to allege any facts creating a plausible inference that any TRT did not conform to Defendants’ specifications. For a failure to test claim, the complaint must allege that the manufacturer “did not conduct proper tests or inspections of a product that it manufactures.” 63 AM. JUR. 2D PRODS. LIAB. § 311 (collecting cases); *see also Wollam v. Wright Med. Grp.*, 2012 WL 4510695, at *3 (D. Colo.). The Darby complaint contains no allegations regarding what tests or inspections were conducted and how any additional tests would have prevented Plaintiff’s injuries. *Messer v. Amway*, 106 F. App’x. 678, 686 (10th Cir. 2004) (Kansas law) (dismissing claim where plaintiff “failed to indicate what tests should have been performed or how any such testing would have prevented her injuries”). These counts should be dismissed.

IV. The loss of consortium claims should be dismissed.

Fourteen wives—Blades, Carpenter, Darby, DeForest, Gibby, Hardee, Hughes, Humphries, Jackson, Jones, King, LaRoche, Lewis, Saylor—bring loss of consortium counts. Those are derivative on their husbands’ causes of action.⁴⁰ The loss of consortium claims should therefore be dismissed for the same reasons that the other causes of action should be dismissed.

CONCLUSION

For the foregoing reasons, the Complaints set forth in Appendix A should be dismissed with prejudice.

manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. *Id.*

⁴⁰ *See, e.g., Meighan v. Shore*, 34 Cal. App. 4th 1025, 1040 (Cal. App. 1995); *Colorado Compensation Ins. Auth. v. Jorgensen*, 992 P.2d 1156, 1164 (Colo. 2000); *Benefield v. Vance*, 726 S.E.2d 531, 534 (Ga. App. 2012); *Kohler v. Fletcher*, 442 N.W.2d 169, 173 (Minn. Ct. App. 1989); *Brouillard v. Prudential Prop. & Cas. Ins.*, 693 A.2d 63, 69 (N.H. 1997); *Trivette v. Yount*, 735 S.E.2d 306, 313 (N.C. 2012); *Rivers v. Otis Elev.*, 996 N.E.2d 1039, 1046 (Ohio. App. 2013); *Knepper v. Brown*, 162 P.3d 1026, 1033 (Or. App. 2007); *Williams v. U.S.*, 754 F. Supp. 2d 942, 955 (W.D. Tenn. 2010); *Brewerton v. Dalrymple*, 997 S.W.2d 212, 217 (Tex. 1999); *Hendricks v. Hurley*, 184 P.3d 680, 687 (Wyo. 2008).

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CERTIFICATE OF SERVICE

I, Scott Ahmad, hereby certify that on June 4, 2014, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Scott Ahmad